REMARKS

Claims 1-41 are pending in the application and have been rejected. Claims 38-41 are new. No claims have been allowed.

TELEPHONE INTERVIEW

The undersigned conducted a telephone interview with Examiner Lang on August 14, 2008. During the interview, the undersigned discussed the background and support concerning the claim term "needle body." The undersigned proposed to amend the term "needle body" to "needle housing," and the Examiner agreed that such amendment would clarify the claims. The Examiner also agreed that the amendment would address the § 112 rejections and had sufficient antecedent basis in the specification. The undersigned wishes to thank the Examiner for the courtesies extended and helpful commentary provided by the Examiner during the interview.

CLAIM REJECTIONS 35 U.S.C. §112

Claims 1-37 were rejected under 35 U.S.C. §112 as being indefinite. As discussed above, the claim phrase "needle body" as used in many of the claims was the source of the rejection. Applicants have thus amended the claims to recite "needle housing" instead of "needle body." The term "housing" is used, among other places, in paragraph 48 of Applicants' specification to refer to the structure also referred to as the "first part of the needle body 2a." Applicants therefore submit that the amendment has full antecedent basis and support in the specification.

AMENDMENTS TO THE SPECIFICATION AND SUBSTITUTE SPECIFICATION

During the interview of August 14, 2008, the Examiner noted that term "needle body" used in the specification as needle body 2a might be clearer if it were amended to read "needle housing." The undersigned agreed to the Examiner's suggestion and an amendment to the specification is submitted herewith. Support for using needle "body" and "housing" synonymously can be found at, among other places, paragraph 48 of Applicants' specification. Applicants submit that no new matter has been added by the amendment to the specification.

Applicants submit herewith a substitute specification in accordance with 37 C.F.R. §§ 1.121(a)(3) and 1.125(b)-(c). Applicants respectfully request that the substitute specification replace the originally filed specification. Applicants assert that the substitute specification does

not introduce any new matter.

REJECTION OF CLAIMS 1-13, 15-18, 20-23, 25, 26, AND 29-32

Claims 1-13, 15-18, 20-23, 25, 26, and 29-32 were rejected as being unpatentable over U.S. Patent No. 5,797,942 to Schraga ("Schraga") in view of U.S. Publication No. U.S. 2003/0114839A1 to Looper ("Looper").

Schraga discloses a reusable end-cap for use with a hand held lancing device. With reference to Fig. 2, lancet system 60 includes a needle 61 and a removable cap 62. Lancet system 60 is manually inserted into the lancet receiving assembly 120 and the device is cocked. The cap 62 is removed (and apparently discarded), and the system cap 10 shown in Fig. 3 (or cap 140 shown in Fig. 1) is then placed on body 110, at which point the device is ready to be used for a lancing operation. See Schraga, col. 5, lines 25-35. The lancet 60 has cross-shaped ridges 65 which apparently are received into the zig-zag shaped grooves of body 120, although the purpose of the ridges and grooves is not disclosed in the Schraga patent. The system cap 10 is provided with engagement means 30 that allows the used needle to be held and removed by cap 10, so as to avoid exposure of a used needle with the user. The central teachings of Schraga relate to the use of engagement means 30 of end cap 10 to avoid unnecessary exposure to a contaminated needle. Compare Figs. 1 and 3; see, e.g., Schraga, Col. 2, line 54 – Col. 3, line 10.

Looper discloses a surgical instrument assembly 110 (Figs. 2 and 3) that includes a hollow manipulation shaft 120 with a prime mover 130 and an interchangeable surgical tool 160 that connects to the prime mover 130 via a coupler 140, and in particular, to a capture member 150. According to Looper, once the end effector 160 has been utilized and contaminated, a frangible portion 200 such as a notch 210 is distorted or severed to prevent connection. As shown in Fig. 2, the frangible portion 200 is either breakable or distortable to prevent proper coupling to the surgical apparatus. Looper, ¶ [0017].

In the previous Office Action of October 18, 2007, the Examiner asserted that cap 62 of Schraga qualified as the protective portion claimed by Applicants. In the instant Office Action, the Examiner instead now asserts that cap 140 (or cap 10) of Schraga qualifies as the claimed protective portion of the needle housing. Applicants' respectfully request that this rejection be withdrawn because it fails to consider the limitations of Applicants' claims.

Independent Claim 1

Claim 1 requires that Applicants' inventive blocking mechanism is "in the needle

housing." Since the Examiner reads the claimed protective portion onto cap 140, and since claim 1 requires that the claimed needle housing comprises the protective portion, this means that cap 140 of the Schraga device has the blocking mechanism. Accordingly, the Examiner's modification of the Schraga device with a "frangible connection" taught by Looper results in the Schraga device having a frangible connection between cap 140 and main body 115. (See Fig. 1 of Schraga).

First, the cap 140 of Schraga is clearly intended to be connected to and disconnected from the main body 115 multiple times, i.e., reused. See Schraga, col. 4, lines 58-60. Configuring the Schraga device with a frangible connection between the cap 140 and main body 115 in accordance with the Examiner's combination of references would destroy this feature and a skilled artisan would therefore avoid it. In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference). McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperable device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.").

Additionally, the Examiner reads the claimed "holding elements" onto the ridges 65 (Schraga, Fig. 2) that apparently are received into the zig-zag shaped grooves. Office Action, pg. 4, lines 16-18. However, claim 1 requires that after removal of the lancet system from the lancing aid, "the holding element of the lancing aid is prevented from interacting with the holding element of the lancet system." Actuation of the Examiner's supposed blocking mechanism would not affect the interaction of ridge 65 and the groove that the Examiner asserts correspond to the holding elements because the Examiner's blocking mechanism is located between the cap 140 and the main body 115, remote from the ridge 65 and groove. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references.)

Further, the Examiner asserts that the claimed "removable lancet system" corresponds to element 60 of Schraga. Office Action, pg. 4, lines 5-7. Apparently, the Examiner is reading the previously claimed "needle body" (now "needle housing") onto the plastic body 60 of the Schraga device, in which the needle 61 appears to be fixed. See Id. (italics added) ("lancet system (60) having a *body* and a needle with a needle tip (61)"). But Applicants' previously presented claim 1 required that the needle be movable mounted to the needle body (now "needle housing"). The Examiner has apparently overlooked this limitation. See In re Fine, 837 F.2d

1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references.) To the extent that the previously used claim term "needle body" has contributed to the Examiner's reading of claim 1, this issue has been addressed by the amendment of "needle body" to "needle housing.

Since the Examiner's combination of references fails to consider at least the claimed features just noted, and since the modification of Schraga would destroy a feature of the Schraga device, Applicants request that the rejection be withdrawn. Further, claims 2-11, depend from claim 1, and so these dependent claims are also non-obvious over the combination of references. Applicants request withdrawal of the rejection of these dependent claims.

Independent Claim 12

Like claim 1, claim 12 recites features that are not disclosed or suggested in the Examiner's combination of references and Applicants thus respectfully request that the Examiner withdraw the rejection. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references); see also MPEP § 2143.03 ("All words in a claim must be considered in judging the patentability of that claim against the prior art.") (quoting, In re Wilson, 4424 F.2d 1382, 1385 (CCPA 1970)).

Claim 12 now requires that the needle housing comprises a blocking mechanism movably connected thereto, wherein the blocking mechanism is actuated by an interaction with a lancing aid and wherein the actuation moves the blocking mechanism relative to the needle housing and changes the shape of the needle housing. Schraga discloses no blocking mechanism at all, as the Examiner admits, and the Examiner relies on Looper for the broad idea of a frangible connection between two parts that removably connect to one another, nothing more. The combination of Schraga and Looper does not disclose the actuation of the blocking mechanism moving the blocking mechanism relative to the needle housing and changing the shape of the needle housing, as claimed.

Furthermore, if the cap 140 corresponds to the claimed needle housing or protective portion, and the holding elements correspond to the ridge 65 and zig-zag groove of Schraga, as the Office Action suggests, then this combination of references fails to address limitations of claim 12 similar to those in claim 1. That is, actuation of the blocking mechanism would not prevent interaction of the holding elements after removal of the lancet system, as claimed. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Further, the Schraga device

modified with the frangible connection between cap 140 and body 115 is destroyed for one of its intended purposes (reusable cap). In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference).

Applicants respectfully request that the rejection be withdrawn. Further, since claims 13, 15-18 and 20 depend from claim 12, they too are nonobvious over the combination of references and withdrawal of the rejection is respectfully requested.

Claim 21

Claim 21 is distinguishable over the combination of Schraga and Looper. As an initial matter, the Examiner did not specify what structure in Schraga she asserts corresponds to the claimed needle housing (formerly "needle body").[1] For example, claim 21 requires a needle housing configured for insertion into a lancing aid and removable therefrom after use. Thus, if the Examiner reads the claimed needle housing on the main body 110 of Schraga or some part thereof, then said needle housing would not be insertable into the lancing aid as claimed. Claim 21 also requires that the needle be movably mounted to the needle housing. If the Examiner reads the claimed needle housing onto element 60, then the needle 61 would not be moveably mounted to such needle housing as claimed.

Finally, if the Examiner instead reads the claimed needle housing on cap 140, which seems most consistent with the Examiner's asserted correspondence between the claimed protective portion and cap 140, other claim limitations are not met and a key feature of the Schraga device is destroyed. Specifically, claim 21 requires that actuation of the blocking mechanism (1) changes the shape of the needle housing and (2) prevents reuse of the needle with the lancing aid after the needle housing is removed from the lancing aid. If the claimed needle housing is read onto cap 140, then the frangible connection of Looper that the Examiner asserts qualifies as the blocking mechanism again must be a frangible connection between cap 140 and body 115, since claim 21 requires that actuation of the blocking mechanism changes the shape of the needle housing. But the cap 140 of Schraga is clearly intended to be connected to and disconnected from the main body 115 multiple times, i.e., reusable. See Schraga, col. 4, lines 58-60. Configuring the Schraga device with a frangible connection between the cap 140 and main body 115 in accordance with the Examiner's combination of references would destroy this

1 Unlike claims 1 and 12, claim 21 does not recite a "protective portion," and the Examiner did not specifically address what element in Schraga corresponds to the claimed needle housing (formerly "needle body"). Thus, alternatives are discussed here.

feature and a skilled artisan would avoid it. See McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperable device,' we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness."); In re Gordon, 733 F.2d 900, 902 (Fed. Cir. 1984) (error to find obviousness where modifying a reference destroys the function or intended purpose of the device disclosed in the reference).

Additionally, even if a skilled artisan were inclined to modify the device of Schraga so as to destroy the reusable cap feature, the Schraga device so modified still fails to consider Applicants' claim limitations. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Namely, actuation of the supposed blocking mechanism would not prevent re-use of the needle after the needle housing is removed from the lancing aid, as is recited in claim 21. While the Examiner's modification undesirably destroys the cap 140 of Schraga, it leaves the needle intact. Thus, e.g., a contaminated needle could be released from the Schraga device, not disposed of properly, and then accidentally be reinserted and reused. This problem is addressed in Applicants specification. See Applicants specification, ¶ 4. The Examiner's modified Schraga device thus does not prevent reuse of the needle once the needle housing is removed. The modified Schraga device would thus suffer a two-fold problem of (1) having a contaminated needle that can be inadvertently re-used after removal from the device and (2) a re-connectable feature between the cap 140 and body 115 that is destroyed.

Applicants respectfully request that the Examiner withdraw this rejection. Further, since claims 22, 23, 25, 26 and 29-32 depend from claim 21, they are also nonovious over this combination of references. Applicants therefore respectfully request that the Examiner withdraw the rejection of these dependent claims.

REJECTION OF CLAIMS 12, 14, 21 AND 24

As in the previous Office Action of October 18, 2007, claims 12, 14, 21, and 24 were again rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2005/0015020 A1 to LeVaughn ("LeVaughn") in view of Looper. The rejection in the present Office Action is different than stated previously because the Examiner has rearranged the correspondence of Applicants' claims and disclosure of Looper as follows:

Claim Recitation	Office Action of 10/17/2008	Office Action of 5/29/2008
Holding element	spring element 74	projection 85
Protective portion	protective cap 147	sleeve 100

The Examiner's new arrangement of claim elements does not consider the limitations in Applicants' claims 12 and 21.

Claim 12

Claim 12 now recites that the needle housing comprises a blocking mechanism movably connected thereto, wherein the blocking mechanism is actuated by an interaction with a lancing aid and wherein the actuation moves the blocking mechanism relative to the needle housing and changes the shape of the needle housing. LeVaughn discloses no blocking mechanism at all, as the Examiner admits, much less a blocking mechanism that is movably connected to a needle housing. The Examiner relies on Looper for the broad idea of a frangible connection between two parts that removably connect to one another, but Looper does not hint or suggest Applicants' claimed blocking mechanism that is movably connected to the needle housing. Since the combination of references does not hint or suggest Applicants' blocking mechanism as recited in amended claim 12, it is respectfully requested that the rejection be withdrawn. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Further, since claim 14 depends from claim 12, withdrawal of the rejection of claim 14 is also requested.

Claim 21

Claim 21 now recites that the needle is movable to and from the lancing position multiple times after the needle housing is inserted into the lancing aid and before removal therefrom. LeVaughn teaches directly away from such feature. As explained in detail in Applicants' Response of July 31, 2007, such claimed feature is not possible with the LeVaughn device because LeVaughn teaches that once a lancet is used for puncture, it is automatically advanced and prevented from returning to the active position. Each lancet can thus only be used once while the cassette 50 resides in the housing of LeVaughn. LeVaughn thus teaches away from Applicants' claim 21. See Ormco Corp. v. Align Technology, Inc., 463 F.3d 1299, 1308 (Fed. Cir. 2006) (reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the

applicant). LeVaughn fails to disclose or suggest a needle that is movable to and from the lancing position multiple times after the needle housing is inserted into the lancing aid and before removal therefrom, as claimed by Applicants. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Applicants thus respectfully request that the Examiner withdraw this rejection. Further, since claim 24 depends from claim 21, withdrawal of the rejection of claim 24 is also requested.

ALLOWABLE CLAIMS 34-37

In the previous Office Action, the Examiner had indicated that claims 19, 27, 28, and 33 would be allowable if rewritten in independent form. Applicants thus submitted with the previous response claims 34-37, which correspond to claims 19, 27-28, and 33, respectively. The only outstanding rejection of claims 34-37 is the § 112 rejection, which Applicants submit has been overcome by the amendment of the claim term "needle body." Applicants' respectfully request allowance of these claims.

NEW CLAIMS 38-41

Claim 38 corresponds to claim 21 as previously presented with the added limitation that the actuation of the blocking mechanism allows at least one area of the needle housing to enlarge. Applicants present this claim since the Examiner has recognized the patentable merit in claims 19 and 27, which recite enlargement of the needle housing. New claims 39-41 were presented in light of the Examiner's suggestion during the telephone interview to recite additional structure of the inventive blocking mechanism. Applicants submit that these new claims are allowable and request allowance thereof.

CONCLUSION

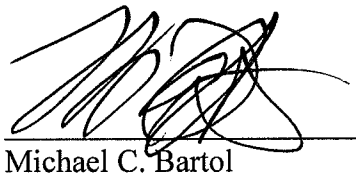
Applicants believe that the foregoing is a complete response to the outstanding Office Action and reconsideration is requested. Specifically, Applicants believe that all claims are now in condition for allowance and allowance thereof is earnestly solicited.

In the event Applicants have overlooked the need for a Petition for Extension of Time or payment of fee (except for Issue Fees), Applicants hereby petition therefor and authorize the United States Patent and Trademark Office to charge any additional fees for extension of time to Deposit Account No. 02-3223, Bose McKinney & Evans LLP.

If the Examiner has any questions regarding any of the foregoing, she is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

BOSE McKINNEY & EVANS LLP



Michael C. Bartol
Reg. No. 44,025

Submitted: September 10, 2008
Bose McKinney & Evans LLP
111 Monument Circle
Suite 2700
Indianapolis, IN 46204

(317) 684-5281

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MARKED-UP COPY OF SUBSTITUTE SPECIFICATION

LANCING AID COMPRISING A LANCET SYSTEM THAT IS PROTECTED AGAINST RE-USE

PRIORITY CLAIM

[0001] This application claims priority to German Application Number DE 103 12 357.1 filed March 20, 2003.

TECHNICAL FIELD

[0002] The invention concerns a lancet system that can be used in a lancing aid for withdrawing blood for diagnostic purposes.

BACKGROUND AND SUMMARY

[0003] In a variety of diseases it is necessary to examine human blood for an analyte contained therein. In many cases this only requires the withdrawal of a small amount of blood in the form of a blood drop by producing a small puncture wound. A particularly important example of such a case is diabetes in which the glucose content of blood has to be examined at regular intervals. Blood may also for example be examined with regard to coagulation parameters, triglycerides, HbA1c or lactate. Blood lancet devices which consist of a lancing aid and a tailor-made replaceable lancet are usually used to produce the required puncture wounds. The housing of the lancet instrument contains a lancet holder in which one interchangeable lancet can be inserted. During the lancing operation the lancet holder is rapidly moved in a lancing direction by a lancet drive of the lancet which is also integrated into the lancing aid until the needle tip emerges from an exit opening provided at the front end of the lancing aid and produces a small puncture wound in the part of the body that is pressed against the front end. Afterwards the lancet holder containing the lancet is moved back in the opposite direction to lancing.

[0004] Small, easy-to-handle blood collection devices, so-called lancing aids that can be easily and reliably operated by the user and enable a part of the body to be lanced in an almost painless manner are now routinely used. In order to avoid infections especially in hospitals, the lancets are disposable elements intended for single use. After a lancet has been used once, the lancet is removed after the lancing operation or ejected from the device and discarded as refuse. In such a case the exposed needles in a refuse container may lead to injury during waste disposal resulting in a contamination of other persons by the used lancet. Such contamination may lead to

infections and thus some countries are planning to impose a ban on blood collection systems in which the needle tip is freely accessible after use. In addition to a risk of injury during waste disposal there is also a risk that a used lancet may be accidentally re-used. This is particularly relevant for hospitals in which a lancing aid is used for several patients since such inadvertence of the nursing staff could lead to a patient being contaminated with the blood of a previous patient.

[0005] In addition to the use of blood lancet devices by medical staff, lancing aids are also used by laymen in the so-called home-monitoring field. This is particularly the case for monitoring the treatment of diabetics. Thus it has been found in the treatment of diabetics that serious damage associated with diabetes such as loss of sight can be substantially reduced when the glucose concentration in the blood of the diabetic is determined frequently and up to five times daily and the insulin injection is exactly adjusted on the basis of these measurements. Lancing aids which enable the diabetic to carry out such a blood examination are used for home-monitoring in order to carry out such frequent measurements. The resulting requirements for a blood lancet device are a simple handling when inserting new lancets and a reliable ejection of used lancets in addition to a simple handling when triggering the lancing operation and a relatively painless puncture. Lancet replacement should on the one hand be as simple as possible and, on the other hand, ensure the utmost safety with regard to unintentional injury of the user or other persons. Although in the home-monitoring field it is conceivable that a lancet, once inserted, is used several times for lancing by the same user, even in this case an accidental re-use of an ejected lancet should be prevented once the user has decided to discard the lancet. Furthermore other persons in particular should be reliably protected from the discarded lancets for example during waste disposal.

[0006] In the prior art the tip of the needle is usually surrounded by a tip cover made of plastic when the lancet is inserted which allows a safe insertion of the lancet. When the lancet is inserted, the tip cover is removed to expose the sharp tip of the needle for the lancing operation (US 5,628,765). However, due to the exposed needle tip there is a risk of accidental injury and the tip may become damaged. The lancet is removed from the lancing aid after one or several lancing operations. This can either be carried out manually in which case there is a high risk of injury by the needle tip or by an automatic ejection mechanism.

[0007] A blood lancet device is disclosed in the patent EP 0 565 970 in which the lancet is ejected from the lancet holder by means of an ejecting rod. The user can operate the ejecting rod by pressing a corresponding button.

[0008] Furthermore an ejecting mechanism is described in the patent document US 4,442,836 where the needle is automatically released when the lancing aid is retensioned so that the used lancet is discarded after each lancing operation. Such ejecting mechanisms require a relatively high degree of additional engineering. Moreover multiple use of an already inserted lancet system is not possible which is, however, often desired by customers especially in the home-monitoring field. Another major disadvantage of the described prior art is that the needle tip is unprotected after the lancet has been ejected resulting in a risk of injury as described above.

[0009] In order to facilitate the safe removal of a used lancet, blood collection systems are also described in the prior art which ensure the needle tip is protected after ejecting the lancet. This is regarded as an important feature especially for elderly users or those that are handicapped by poor sight and shaking hands as a result of disease.

[0010] A protection of the needle tip is achieved in the prior art by integrating the lancet in a cap of the lancing aid such that the lancet and the housing cap together form a replaceable disposable unit. Such designs are described in the documents EP 0595148 and US 4,990,154, US 5,454,828 and DE 10053974. When the lancet is ejected by the user, the housing cap is placed over the needle tip so that the lancet surrounded by the cap can be subsequently discarded. Even if the needle tip is protected after ejection by the described mechanism, it is nevertheless possible for a careless user to reinsert a needle that has already been ejected once and carry out a new lancing operation. Consequently the user is instructed to recognize that the needle has already been used.

[0011] Only the document EP 0 630 609 discloses a mechanism which directly prevents reinsertion and thus re-use of a lancet that has been ejected once. The described lancet device comprises a needle with a needle body which breaks when the needle is ejected from the lancing aid to prevent a reinsertion of the needle. This prevents the user from re-using a contaminated needle. However, a disadvantage of the prior art is that the needle tip is unprotected after the needle has been ejected.

[0012] The object of the invention is to provide an easy-to-use lancing aid preferably for the home-monitoring field which prevents re-use of an already ejected lancet system and also

ensures a protection from injury by the needle tip after the lancet system has been ejected. It should advantageously be possible to easily reuse a needle of a lancet system that has been inserted once.

[0013] The object is achieved by a lancing aid and a lancet system according to the independent claims. Preferred embodiments are derived from the dependent claims.

[0014] The invention concerns a lancet system and a lancing aid containing the lancet system. The lancing aid has a housing for inserting a lancet system. The housing also has an opening where the needle tip can emerge from the housing and a drive mechanism for carrying out a lancing operation.

[0015] According to the invention the housing additionally has a holding element which can interact with a corresponding holding element of the lancet system as soon as the lancet system has been inserted in the lancing aid. The interaction between the holding elements enables the lancet system to be positioned in the housing at a defined site. An exact positioning of the lancet system is important especially with regard to the drive mechanism for the lancing aid since it is the only way in which the needle can be correctly coupled to the drive mechanism such that the needle can perform a lancing operation at high speed and almost without vibration. This enables a rapid and relatively painless puncture in the intended part of the body. In addition to the described holding element, the lancet system for the lancing aid comprises at least one needle with a tip which is suitable for producing an opening in the skin. The needle is connected to a needle ~~body~~ housing and at least one protective portion of the needle ~~body~~ housing and the needle can be ~~removed~~ moved relative to one another. In a first position the needle tip is at least partially surrounded by the protective portion of the needle ~~body~~ housing whereas in a second position the protective portion of the needle ~~body~~ housing and the needle tip are disposed relative to one another such that the needle tip is released from the protective portion of the needle ~~body~~ housing. If the protective portion of the needle ~~body~~ housing is in its first position, it thus guards against injury by the lancet tip which is particularly important after the lancet system has been ejected from the lancing aid.

[0016] The needle ~~body~~ housing also contains a blocking mechanism which is activated by an interaction with the lancing aid. The blocking mechanism changes the needle ~~body~~ housing in such a manner that after the lancet system has been ejected from the lancing aid, the holding element on the lancing aid can no longer interact with the holding element of the lancet system

when it is reinserted. This prevents re-use of a lancet system that has been ejected once. In this connection the blocking mechanism can be automatically actuated as soon as certain operating steps have been carried out on the lancing aid. However, other embodiments are conceivable in which the user actuates the blocking mechanism by a separate operating step.

[0017] As a result of the special design of the needle ~~body~~ housing, the lancet system according to the invention provides a protection from the needle tip such that after ejection from the lancet system the tip is surrounded by the protective portion of the needle ~~body~~ housing to such an extent that injury by the tip is prevented. The blocking mechanism also influences the interaction of the holding elements. Within the scope of the invention the term interaction of the holding elements encompasses any conceivable embodiment that is known in the prior art for inserting and positioning a lancet or a magazine in a lancing aid. For example the holding elements can be snapped in or clamped. Suitable holding elements for this may for example be designed as locking lugs, grooves or hooks to name only a few possible embodiments. Similarly to the systems described in the prior art containing individual lancets, it is also conceivable that the lancet system is already adequately positioned and held in the lancing aid due to its coupling to the drive unit so that for example the drive unit itself can be used as a holding element for an appropriately designed lancet system.

[0018] If several holding elements are provided to position the lancet system, the blocking mechanism advantageously prevents an interaction between the holding elements of the lancet system and the lancing aid so that the lancet system cannot be held and positioned in the lancing aid. This is particularly advantageous when the lancet system and lancing aid each have several holding elements that act independently of one another.

[0019] In a preferred embodiment the interaction of the holding elements is blocked in such a manner that the lancet system is prevented from being reinserted in the lancing aid. Within the scope of the invention the term "reinsertion" encompasses a handling of the lancet system such that the lancet system is positioned at the position in the lancing aid intended for carrying out the lancing operation and is held there due to the interaction of the holding elements. For this purpose the lancet system is again used at its original position in the lancing aid thus restoring the original state of the lancet system and lancing aid which was present when the lancing aid was first used.

[0020] When operating the lancing aid, the user can advantageously immediately and unambiguously identify an already used lancet system for example due to the fact that a reinsertion of the lancet magazine into the lancing aid is blocked. Hence in contrast to the prior art the user is not required to consciously distinguish between a used lancet system and a new lancet system. Advantageously the user is spared an unnecessary reinsertion of a used lancet system which no longer functions which elderly and visually handicapped persons often find to be difficult.

[0021] However, it is also possible that the blocking mechanism only blocks the lancing operation in which case it is possible to reinsert a needle that has already been ejected. If a reinsertion of the lancet system is prevented, this usually means that the lancet system cannot couple to the drive unit.

[0022] In a preferred embodiment the blocking mechanism is essentially achieved by a change in the shape of the needle ~~body~~ housing. This proves to be particularly advantageous when the shape of the needle ~~body~~ housing itself forms at least a part of a holding element. It is also possible that a deformation of the needle ~~body~~ housing spatially separates the holding elements in the lancing aid such that the blocking mechanism has an indirect effect on a holding element without directly acting on it. Hence the lancet system can no longer be positioned and held at a defined position in the lancing aid. In a preferred embodiment the deformation of the needle ~~body~~ housing transfers the protective portion of the needle ~~body~~ housing to a first position such that there is no risk of injury when disposing a used lancet. The protective portion of the needle ~~body~~ housing and the blocking mechanism are then achieved as a single component of the lancet system.

[0023] In principle the holding elements can interact in a variety of ways. The blocking mechanism may have a direct or indirect effect on the holding elements. In the case of a direct effect on the holding elements, at least one holding element is advantageously changed, covered or destroyed in such a manner that interaction of the holding elements is no longer possible. Furthermore embodiments are also conceivable in which the lancet system is positioned within a lancing aid due to magnetic properties of the system. Hence a change in the magnetic properties of the needle ~~body~~ housing could prevent a re-use of the lancet system. Appropriate magnetic elements of the needle ~~body~~ housing or lancing aid are then the holding elements of the system.

[0024] Since the blocking mechanism advantageously only prevents a repeated insertion of the lancet system but does not prevent re-use of a needle that has already been inserted, the lancet system also satisfies requirements in the home-monitoring field where multiple use of a once inserted needle is often desired.

[0025] The lancing aid according to the invention for collecting blood has a drive unit with a plunger which moves a needle from its resting position into a lancing position. A number of drive mechanisms are known in the prior art that can be used in the field of blood collection devices (e.g. US 5,314,442, WO 00102482, US 3,030,959). In particular drive mechanisms are frequently used which draw their energy from a previously tensioned spring. Drive units are preferably used within the scope of the present invention which enable a guided movement of the plunger and needle for example as a result of a form-fitting coupling as described in the document DE 10053974. Guided movements of the needle for example by means of guide blocks have also been previously described in EP 0 565 970. Such drive mechanisms are preferred because the puncture is less painful. However, the system according to the invention is not limited to a particular drive mechanism, but on the contrary, can be combined with a variety of drive units.

[0026] An important aspect of the invention is a lancet system that can be detached from the drive unit containing at least one needle where the lancet system is provided as a disposable unit. In this connection the term needle encompasses a blade-shaped substantially flat lancing unit and all other conceivable embodiments thereof. In principle needles can be used for the invention that are basically well known in the prior art and can be used in a lancet system. In the prior art a needle is often combined with a base body that can couple to the lancing aid which is referred to as a lancet. Such lancets often have a base body made of plastic in which a metal needle is disposed. According to the invention it is possible to integrate such a lancet into the lancet system according to the invention. It is for example conceivable that the needle ~~body~~ housing according to the invention contains a base body like that used for lancets in the prior art, where the inventive functionality of the system is maintained by integration of the base body. In this case the ~~needle body~~ lancet system has an at least two-part design according to the described embodiment. In a preferred embodiment the needle ~~body~~ housing is designed such that a plurality of lancets is disposed in the needle ~~body~~ housing such that the needle ~~body~~ housing represents a magazine containing a plurality of lancets and each base body of the lancet

represents a needle body. Consequently in a preferred embodiment the protective portion of the needle ~~body~~ housing is formed by the magazine housing. The needle and the base body can then be guided in a movable manner within the magazine. The needles within a needle ~~body~~ housing designed according to the invention as a magazine are preferably present in separate chambers in order to prevent contamination of unused needles by used needles when reloading.

[0027] In order to carry out a lancing operation, portions of the needle body are advantageously designed like the system already described in DE 10053974 such that the individual needles of the system can be actively coupled to the drive unit of the lancing aid. Embodiments that can also be used to drive needles within a magazine of a lancing aid are described for example in the documents DE 10053974, US 4,990,154 and US 5,074,872. The chambers arranged next to one another in which the lancets are individually located are positioned successively relative to the drive unit in order to carry out a lancing operation in such a manner that in each case a single needle can be coupled to the plunger of the drive unit. Also in this case magazines in the form of a drum containing chambers in which the needles are located parallel to the longitudinal axis of the drum have also proven to be particularly advantageous.

[0028] The lancet system also advantageously comprises a needle ~~body~~ housing which at least partially surrounds the needle tip by the protective portion of the ~~body~~ housing when the needle is in its resting position. In order to carry out the lancing operation, the protective portion of the needle ~~body~~ housing is spatially separated from the needle tip so that the protective portion of the needle ~~body~~ housing does not hinder the lancing operation. When the lancet system is ejected from the lancing aid the needle remains in its resting position so that the ejected needle tip is protected and additionally the blocking mechanism according to the invention prevents a re-use of the lancet system. It is, however, also possible that the protective portion of the needle ~~body~~ housing is not transferred to its first position until the lancet system is ejected so that the needle tip is only protected as a result of the ejection. In a preferred embodiment an unused needle is also in a resting position before insertion into the lancing aid to prevent injury by the needle tip and contamination when the needle is inserted as well as after ejection.

[0029] A blocking mechanism according to the invention can be actuated for example when the lancet system is ejected from or inserted into the lancing aid independently of the needle tip protection. In principle the blocking mechanism or the needle tip guards can also be activated separately or by means of individual operating steps of the lancing aid e.g. during the

lancing operation. In general all possible combinations are conceivable which ensure a simultaneous or successive blocking mechanism and protection of the needle tip.

[0030] The blocking mechanism can have a variety of designs but it is advantageous that the shape of the needle ~~body~~ housing is changed in such a manner that it is no longer possible to reinsert a lancet system once it has been ejected. For example the blocking mechanism can move at least one part of the needle ~~body~~ housing that interacts with the lancing aid in such a manner that a change in its position blocks a reinsertion of the lancet system. This is for example the case when the blocking mechanism closes a recess in the needle ~~body~~ housing which forms a holding element or a recess is generated in the needle ~~body~~ housing that is essential for an interaction of the lancet system with a lancing aid. Furthermore it is also possible that the blocking mechanism comprises a predetermined breaking point which results in a breaking of the needle ~~body~~ housing when the lancet system is ejected. It is also conceivable that the needle ~~body~~ housing is enlarged, made smaller or bent which are only a few methods for deforming the needle ~~body~~ housing.

[0031] According to the invention an interaction between the lancet system and lancing aid activates the blocking mechanism and sets a first position of the protective portion where the protective portion at least partially surrounds the needle tip.

[0032] An important requirement for the lancet system is that the needle tip that is used to produce a wound in an appropriate part of the body is sterile. The sterility of the needle tip has to be ensured over a long period which extends from the manufacture of the lancet system up to its use. Sterility can be achieved during the manufacture of the lancet system by for example gamma radiation which is commonly used in the prior art. In order to maintain sterility, the lancet system can be sealed in a wrapping, for example a polyethylene bag. In another embodiment the opening of the lancet system where the needle tip emerges from the protective portion of the needle ~~body~~ housing can for example be closed by a sealing foil. These are preferably detachable sealing foils which the user removes before using the lancet system. However, it is also possible to use thin foils which are not pierced by the needle tip until the needle is used so that the user does not have to carry out additional handling steps. Such foils may already be used as an integral part of the manufacturing process for the lancet system which is usually by means of an injection moulding process.

[0033] Furthermore in the prior art an elastomer is described in the application WO 01/66010 for sterile protection which encloses the needle tip and thus protects it against

contamination. This sterile protection can either be pierced during the lancing operation or be removed by the operator before use.

[0034] In another advantageous embodiment the protective portion of the needle ~~body~~ housing can comprise a sterile protection and/or the protective portion can be essentially formed thereby. In this case the elastomer of the sterile protection serves for example as the protective portion of the needle ~~body~~ housing by the fact that the needle tip can be moved in a guided manner relative to the elastomer. Another part of the needle ~~body~~ housing that can be actuated independently of the sterile protection is able to change the needle ~~body~~ housing and represents the blocking mechanism. This requires that the sterile protection can reversibly expose the needle tip and surround it again which is for example the case with an elastomer protection (WO 01/66010) in which the elastomer is firstly pierced during the lancing operation and subsequently the needle tip is retracted into the elastomer. Consequently in this example the needle tip changes its position relative to the sterile protection during the lancing operation and the needle tip is protected by the sterile protection in its resting position after the lancing operation. In principle many embodiments of a sterile protection are conceivable and hence the inventive system is not limited to any special embodiment of a sterile protection.

[0035] Further features and advantages of the invention will become apparent from the following discussion and the accompanying drawings in which: The system according to the invention is illustrated in the following on the basis of the figures and examples without being thereby limited to the individual examples.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] FIG. 1 (a) to FIG. 1 (d) is a perspective view of a two-part lancet system;

[0037] FIG. 2 (a) to FIG. 2 (d) is a perspective view of the Lancet system in which the blocking mechanism is activated during the lancing operation;

[0038] FIG. 3 (a) to FIG. 3 (f) is a perspective view of the blocking mechanism that is activated when the system is ejected;

[0039] FIG. 4 (a) to FIG. 4 (d) is a perspective view of the Lancet system with a blocking mechanism which prevents a lancing aid from coupling to the lancet system;

[0040] FIG. 5 (a) to FIG. 5 (c) is a perspective view of the Lancet system with a blocking mechanism which is activated when it is inserted in the lancing aid;

[0041] FIG. 6 (a) to FIG. (h) is a perspective view of the Lancing aid with a lancet magazine; and

[0042] FIG. 7 (a) to FIG. 7 (e) is a perspective view of the Lancet system with a blocking mechanism which widens the needle ~~body~~ housing.

DETAILED DESCRIPTION

[0043] The following description of the preferred embodiment is merely exemplary in nature and is in no way intended to limit the invention or its application or uses.

[0044] FIG. 1 shows a lancet system (1) which is essentially in two parts. FIGS. 1b and 1d each show a cross-section through the lancet system shown in FIGS. 1a and 1c before and after use respectively. The system has a needle (3), the front tip of which is wrapped in a sterile manner with an elastomeric protection (4). Such elastomers which ensure the sterility of the needle tip are known for example from the document WO 01/66010 to which reference is herewith made. The metallic needle (3) is attached to a plastic body (2b) and is permanently connected thereto. The plastic body has a rear portion (6) which couples the lancet system to a drive plunger such that the needle can be moved along the axis (8) in the direction of lancing. The rear portion (6) of the plastic body which is a part of the needle body comprises two arms which can connect in a form fitting manner during the lancing operation with a drive plunger of a lancing aid (not shown) by means of the projecting parts (11). A form-fitting connection between a drive plunger and lancet is described for example in the document DE 10053974 to which reference is also herewith made. Of course any other coupling mechanism that is described in the prior art is conceivable for carrying out the lancing operation. The needle (3) and the plastic body (2b) that is permanently connected thereto are movably mounted in the plastic ~~body~~ housing (2a) which represents the protective portion ~~of the needle body~~. The needle and ~~the second part of the~~ needle body (2b) can be moved within this needle ~~body~~ housing along the direction of lancing. The protective portion of the needle ~~body~~ housing (2a) has a lower wall (10) which has a hole (9) through which the needle tip can emerge during the lancing operation. The needle ~~body~~ housing also has an opening (7) at its upper end through which a drive plunger of a lancing aid can be inserted into the needle ~~body~~ housing in order to connect in a form-fitting manner with the ~~second part of the~~ needle body and perform the lancing operation. The protective portion of the needle ~~body~~ housing (2a) also has two recesses (13 and 14) which allow it to be locked into the ~~second part of the~~ needle body (2b). In order to enable the ~~second part of~~

~~the~~ needle body to engage in the protective portion, the rear portion (6) of ~~the second part of~~ the needle body also has locking lugs (12) which engage in the recesses (14) in a first resting position of the lancet system before use and hold the ~~second part of the~~ needle body due to the spread arms (6). The middle portion of the protective portion and of the ~~second part of the~~ needle body have trough-shaped taper (5 and 5') ~~of the body~~ such that the tapered parts (5 and 5') exactly fit together in the first resting state before the lancet system is used and the lancet system in this position has the design shown in FIG. 1a.

[0045] In order to carry out the lancing operation, a plunger (not shown) of the lancing aid engages through the opening (7) into the lancet system where the plunger connects in a form-fitting manner with the arms (6) of ~~the second part of~~ the needle body. As a result the arms (6) are pressed together so that the lugs (12) of the arms (6) no longer engage in the recesses (14) and the needle can be moved forwards along the lancing direction (8). In this process the elastomeric protection (4) is firstly pressed against the lower wall (10) of the needle ~~body~~ housing (2a). If the lancing operation is continued the needle is driven through the elastomeric protection and can thus emerge from the opening (9) in the lower wall (10) and produce a wound in the intended part of the body. The elastomeric protection (4) is meanwhile held back by the wall (10) as a result of which the front part (15) of ~~the second part of~~ the needle body (2b) corresponding to the recess (16) can move over the elastomeric protection. After the lancing operation has been carried out, the needle body (2b) and the needle are subsequently retracted into the protective portion (2a) due to the form-fitting coupling to the drive plunger. Once the rear arms (6) are in the rear protective portion of the needle ~~body~~ housing (2a), the lugs (12) can engage in the recess (13) of the needle ~~body~~ housing (2a) when the needle body (2b) is pulled back. The lancet system is now in a second resting position after the lancing operation. In this position the second part of the needle body (2b) protrudes from the opening (5) of the protective portion of the needle ~~body~~ housing (2a) in such a manner that the needle body is deformed in this area. The tapered parts (5 and 5') no longer fit together. In a lancing aid designed in a corresponding manner which only allows insertion of a lancet system when the tapered part (5) of the needle body is completely formed according to FIG. 1a, insertion of an already used lancet system is blocked according to FIG. 1c.

[0046] The example shown in FIG. 1 has a blocking mechanism and enables the protective portion of the needle ~~body~~ housing to be transferred to a first position during the

lancing operation. When the lancet system is ejected after the needles have been used, the shape of the system has already been changed in such a manner that it is no longer possible to reinsert the lancet system in an appropriately designed lancing aid. Furthermore the needle tip is completely surrounded by the protective portion and hence there is no risk of injury for other persons e.g. during waste disposal.

[0047] FIG. 2 shows a lancet system in the form of an essentially round lancet magazine. In comparison with FIG. 1 the protective portion of the needle ~~body~~ housing (2a) is only designed as a magazine so that a plurality of needles (3) can be movably guided therein.

[0048] FIG. 2a shows an outer view of a magazine. The magazine housing which forms the protective portion ~~of the needle body~~ is designed similarly to FIG. 1 and has recesses (13 and 14) into each of which the locking lugs (12) of the respective ~~second part of the~~ needle body (2b) can engage. The lancet system has a magazine axis (21) that is arranged concentrically in the protective portion ~~of the needle body~~ and is used as a bearing for the lancet system in a lancing aid. The lancet system can be rotated around the axis (21) so that one needle in each case can be positioned relative to a drive unit (not shown) in the lancing aid. Like the lancet system shown in FIG. 1, the lancet system in FIG. 2 also has tapered parts (5) within the protective portion ~~of the needle body~~ (2a) which are in the form of openings where the openings are also essentially tightly closed by ~~the second part of~~ the needle body (2b).

[0049] FIG. 2b shows a cross-section through the lancet magazine shown in FIG. 2a. The system has a similar structure to that of FIG. 1, but consists of a plurality of needles that are equipped with an associated ~~second part of the~~ needle body (2b). Consequently the lancet system shown in FIG. 2 has several parts which include an outer protective portion ~~of the needle body~~ and several ~~second parts (2b) of the needle body~~ needle bodies 2(b). FIGS. 2c and 2d show the lancet system after use in which all needles of the lancet system have already been used for lancing. It is of course also possible that only some of the needles have already been used in the lancet system. In this case the ~~second part (2b) of the~~ needle body (2b) would only protrude through some of the openings (5) of the protective portion ~~of the needle body (2a)~~ whereas the other openings would be tightly closed by the needle ~~body~~ housing as shown in FIG. 2a. Depending on how the lancet system interacts with the lancing aid, embodiments are conceivable where reinsertion of the lancet system into a lancing aid is already blocked as soon as some of the needles have been used or is only blocked after all needles have been completely used in the

lancet system. Advantageously it is also conceivable that the reinsertion of a partially used lancet system into the lancing aid is only possible when the system has been positioned relative to the drive plunger in such a manner that only unused lancets can be used by the system.

[0050] FIG. 3 shows a rectangular needle ~~body~~ housing which also comprises a plurality of needles in the form of a magazine. The protective portion of the needle ~~body~~ housing (2a) also has openings (9) in its lower end (10) from which the needles can emerge to perform a lancing operation. While in their resting position i.e. when no lancing operation is carried out, the needle tips of the needles (not shown) are within the protective portion of the needle ~~body~~ housing (2a) in which the needles can be movably guided. The needle ~~body~~ housing (2a) contains grooves in a lower portion (34) that borders the lower end (10) of the needle ~~body~~ housing which make it easier to grip and thus facilitate its handling by the user. Recesses (33) are provided in this portion (34) as holding elements which, in an appropriately designed lancing aid, enable the lancet system to lock into the lancing aid during insertion. The blocking mechanism (31) is located in the middle of the needle ~~body~~ housing (2a) as part of the needle ~~body~~ housing (2a) and can be movably guided to an upper portion (35) of the needle ~~body~~ housing (2a), and is firstly held in a starting position by spring-mounted arms (39). There is also a recess (32) in the upper part (35) which locks the blocking mechanism (31) when the blocking mechanism (31) is guided along the upper part of the needle body (35).

[0051] FIG. 3b shows the lancet system after use. As illustrated in FIG. 3b, the blocking mechanism (31) that surrounds the needle ~~body~~ housing (2a) in the form of a ring is now positioned at the upper end of the needle ~~body~~ housing so that the blocking mechanism (31) in this position widens the needle ~~body~~ housing section (35). Once the blocking mechanism (31) has been locked into its position, it is no longer subsequently possible to reinsert the lancet system due to the enlarged needle ~~body~~ housing.

[0052] FIGS. 3c and 3d illustrate in more detail the operation of the blocking mechanism (31) which is used in the lancet system described above. In order to lock the blocking mechanism (31) in the upper portion (35), the blocking mechanism has locking arms (36) which engage in the recesses (32). In the position shown in FIGS. 3b and 3c the locking arms (36) are spring-mounted against the lower edge of the recess (32) to secure the blocking mechanism (31) against displacement. The stop (37) also serves as an additional counter-flange of the blocking mechanism (31) against the projection (38) in the upper portion of the needle ~~body~~ housing

component (35). When the magazine is inserted as shown in FIG. 3e for first use in a lancing aid housing (70), the rear portion (35) of the magazine housing is positioned in an appropriately tapered position (82) of the housing (70). In contrast the front portion (80) of the housing (70) is widened so that the widened diameter of the lancet system due to the ring that acts as the blocking mechanism can be placed accordingly in the lancing aid housing. In this position the lancet system is held in the lancing aid in such a manner that a drive unit (not shown) of the lancing aid can engage in the magazine housing in order to couple onto a needle of the lancet system. The lancing aid housing also has two stops (83, 84) which are adjacent to the blocking mechanism (31) in this position of the lancet system in the lancing aid. If the lancet system is removed from the lancing aid housing after use, the stop (84) firstly has the effect that the blocking mechanism (31) remains fixed in position in the lancing aid housing while the magazine housing is pulled out of area (82) of the lancing aid. As a result the blocking mechanism (31) is pushed along the needle ~~body~~ housing to the upper portion (35) of the needle ~~body~~ housing. In this process the blocking mechanism (31) locks with the needle ~~body~~ housing and the projection (38) and the stop (37) block further movement of the blocking mechanism along the needle ~~body~~ housing. If the blocking mechanism (31) rests against the projection (38), a further pulling movement on the magazine housing overcomes the resistance of the stop (84) and the magazine can be removed from the lancing aid. The magazine is now outside the housing in a used state as shown in FIG. 3b where the blocking mechanism (31) is permanently positioned on the needle ~~body~~ housing due to the locking hooks (36) and the stop (37). If the lancet magazine is reinserted into the lancing aid housing, the magazine can no longer be pushed into the tapered area (82) of the lancing aid due to the widened circumference of the upper section (35) of the needle ~~body~~ housing. Hence it is no longer possible to position the lancet system in its original position in the lancing aid. The lancet system can no longer be held in the lancing aid. The coupling of individual needles to the drive unit of the lancing aid in order to carry out a lancing operation is blocked. Moreover after the lancet system has been ejected, the user can easily visually recognize that the lancet system is a used system due to the displaced ring. For this purpose it is also conceivable that the blocking mechanism (31) is highlighted in color.

[0053] As an alternative to the described change in the needle ~~body~~ housing (2a), it is for example also conceivable that the blocking mechanism (31) can be moved over the recesses (33)

of the lancet system. In this case a reinsertion of the lancet system in a lancing aid would be prevented because the lancet system could no longer lock into the lancing aid. Other embodiments using a movably mounted blocking mechanism are conceivable which for example result in a reduction in the size of the upper section (35) of the needle ~~body~~ housing. In this case an unused lancet system e.g. in the state shown in FIG. 3b, is firstly placed in a lancing aid. A used lancet system would then be characterized in that the blocking mechanism (31) would have been pushed over the needle ~~body~~ housing portion (35) in such a manner that the upper section (35) of the needle ~~body~~ housing (2a) is diminished in size. FIG. 3a would thus represent the ejected state of the system. A correspondingly designed lancing aid would then for example have holding elements that could no longer interact with a lancet system that has been changed in this manner and reinsertion into the lancet system would no longer be possible. The locking elements of the blocking mechanism and of the needle ~~body~~ housing (2a) would then have to be adapted accordingly. Furthermore it is also conceivable that a movable blocking mechanism (31) ensures that a reinsertion of the lancet system is blocked and also protects the needle tips. In this case the needle tips would not, as shown in FIG. 3, be retracted into a protective portion of the needle ~~body~~ housing after the lancing operation. Hence the needle tips would not be automatically protected in a resting position. For example protection from the needle tips would not be ensured until the lancet system has been ejected from the lancing aid. According to the blocking mechanism shown in FIG. 3a, a movement of the blocking mechanism (31) elongates the needle ~~body~~ housing in the area of the needle tips so that the needle tips are surrounded in a protective manner by the blocking mechanism and at the same time the blocking mechanism is activated due to a change in the shape of the ~~body~~ housing. In this case a part of the needle ~~body~~ housing acts as a blocking mechanism and also as a protective portion of the needle ~~body~~ housing which surrounds the needle tip area when the lancet system is ejected. The protective portion of the needle ~~body~~ housing and the blocking mechanism then comprise one structural element of the needle ~~body~~ housing.

[0054] FIG. 4 shows a rectangular lancet system in which several needles are positioned in chambers (42) of the protective portion of the needle ~~body~~ housing (2a). The upper section of the protective portion of the needle ~~body~~ housing has a blocking mechanism (41) in the form of a button which is located above the protective portion of the needle ~~body~~ housing and can be moved along direction (45) towards the protective portion of the needle ~~body~~ housing. The upper

part of the button has a guide groove (49) which engages in a matching lip of the lancing aid (not shown) so that the lancet system can be securely positioned in the lancing aid. Once positioned in this manner, a drive plunger of the lancing aid (not shown) can couple with the rear area (48) of the needle (3) to carry out a lancing operation. For this purpose the needle is moved along direction (43) relative to the protective portion of the needle ~~body~~ housing and the needle tip emerges from the protective portion (2a) of the needle ~~body~~ housing. As in the systems that have already been described, the needles are returned to the magazine after the lancing operation and the needle tip is retracted within the needle ~~body~~ housing (2a). The magazine is moved to the next position by moving the drive plunger of the lancing unit along direction (44) until the plunger can couple with a needle positioned in the adjacent chamber (42) in order to carry out a new lancing operation. If the lancet system has to be replaced in the lancing aid, the drive plunger must firstly be moved outside the rear area (46) of the needle ~~body~~ housing (2a). For this purpose the magazine is moved to the next position and at the same time the button (41) is pressed down by a ramp on the housing of the lancing aid. The button (41) is now shifted within the lancet system as shown in FIGS. 4c and 4d so that the section (50) of the button protrudes from the bottom of the needle ~~body~~ housing (2a). In this position a recess (47) of the button (41) engages the rear area (48) of the needle (3) which prevents the lancing aid from coupling again with the lancet system as shown in the front view of FIG. 4d. Hence a lancing operation cannot be carried out with a lancet system of FIG. 4c or d. Moreover the lancet system cannot be reinserted into the lancing aid due to the change in the shape of the needle ~~body~~ housing in area (50). Hence the lancet system cannot be positioned via the guide groove (49) as part of a holding element.

[0055] FIG. 5 shows a round-shaped lancet system which also contains several needles within the needle ~~body~~ housing. Similarly to FIG. 2, the lancet system has a multipart needle ~~body~~ housing. A channel (52) is arranged along the axis of rotation of the lancet system and a plug (53) is located in this channel at the upper end of the lancet system. The plug (53) is held in its first position by expanding holding arms (56) and this position represents the unused state of the lancet system. The holding arms (56) engage in a taper of the plug (53) which is formed by planes (55) of the plug which slant towards one another. When the lancet system is inserted into a lancing aid (70) the plug (53) is pressed within the channel (52) towards the needle tips by means of a centering plunger (57) of the lancing aid. The holding arms (56) are spread when the

plunger is pressed in due to the slanting planes (55) of the plug (53). When the holding arms (56) of the lancet system are spread the plunger (57) can engage between them. Hence the plunger (57) can be almost completely inserted into the lancet system and is used as a bearing for and to position the magazine. An appropriately designed drive unit of the lancing aid can thus be oriented relative to the lancets of the system such that it can be coupled to a lancet and a lancing operation can be carried out. After the magazine has been used it is removed from the lancing aid. For this purpose the plunger (57) is pulled out from the interior of the magazine housing while the plug (53) remains at the lower end of the magazine in the area of the needle tips. Consequently a used lancet system is designed as shown in FIG. 5c in which the plug (53) is no longer held in the upper section of the holding arms (56). If an attempt is made to insert the used lancet system into the lancing aid, the plunger (57) strikes the upper portion (56) of the holding arms which in their unspread state prevent the plunger from penetrating into the lancet system. The absence of the plug (53) prevents the plunger (57) of the lancing aid from spreading the holding arms and thus the lancet system cannot be placed in the lancing aid.

[0056] FIG. 6 shows another embodiment of a lancet system that is arranged within a lancing aid. FIGS. 6a to 6d firstly show a lancet system that is similar to that of FIG. 1. Like FIG. 1 the system shown in FIG. 6 also has an elastomer (4) which surrounds the needle tip in a sterile manner and a ~~two-part~~ needle body and needle housing combination which has a taper (5, 5') in its middle. The needle body (2b) whose movement is guided in the interior of the protective portion of the needle ~~body~~ housing (2a) also has arms (6) in its rear section which can couple in a formfitting manner with a plunger (78) of the lancing aid (72). As shown in FIGS. 6b and c, the plunger (78) engages with a head (71) in the ~~second part (2b) of the~~ needle body (2b) and moves the needle along the axis (8) in the direction of lancing. In this process the arms (6) of the needle body (2b) are pressed together and the projections (11) engage behind the notches in the head (71). The mode of operation of the lancet system is similar to that already described in FIG. 1 and is thus only shown again here with regard to its interaction with the lancing aid. The lancing aid (72) has a locking lever (74) that is mounted in the lancing aid and is rotatably pivoted on an axis (75). The locking lever (74) has a circular shape in a first area (77) such that the locking lever can engage in a form-fitting manner in the taper (5) of the lancet system.

[0057] FIG. 6a shows the state of the lancing aid with the lancet system before use in the inserted state. If it is intended to use the lancing aid for a lancing operation, the locking lever

(74) is rotated by about 90° either automatically when a lancing operation is triggered or separately by the user, such that the lower section (77) of the locking lever no longer engages in the taper (5, 5'). The rotation of the locking lever is ensured by the fact that the lancing aid also has a depression (76) in the housing of the lancing aid which allows the locking lever to rotate around the axis of rotation (75). When the lancing operation is carried out, the ~~second part of the~~ needle body (2b) can move along the protective portion of the needle ~~body~~ housing (2a) and a section of the needle body (2b) emerges from the opening of the needle ~~body~~ housing (2a) without being hindered by the locking lever (74). In this process the needle tip is driven through the elastomer and the exit opening (9) of the lancet system and through an exit opening (73) of the lancing aid.

[0058] After the lancing operation the needle returns to its resting position during which, however, the ~~second part of~~ needle body locks into the recess (13) of the protective portion of the needle ~~body~~ housing. As already described in FIG. 1, this results in a change in the outer shape of the needle ~~body~~ housing in the area of the taper (5) since ~~the second part of~~ the needle body (2b) now protrudes from the opening of the needle ~~body~~ housing (2a). After the lancet system has been removed from the lancing aid, the locking lever (74) rotates back into its initial position as shown in FIG. 6a. As indicated in FIG. 5d, a reinsertion of the lancet system into the lancing aid is blocked by the locking lever (74). The locking lever (74) can no longer engage in the taper (5) of the used lancet system since the taper (5) is partially closed by ~~the second part of~~ the needle body (2b). Hence the lancet system can no longer be positioned and thus held in its original position. The plunger (78) can no longer engage in the lancet system. The head (71) and the projections (11) are prevented from forming a form-fitting connection.

[0059] FIGS. 6e - 6h show embodiments similar to FIGS. 6a - 6d in which the lancet system consists of a plurality of needles so that they can be stored in a magazine as shown in FIG. 2. The operating principles are, as already described, identical and can be simply transferred from the system with one needle to the system shown in FIGS. 5e - 5h. At this point the intention is only to illustrate an embodiment that allows a magazine to be reinserted whose needles have only been partially used. For this the user must rotate the magazine relative to the lancing aid housing until the locking lever (74) can engage in a taper (5) which is not blocked by a needle body (2b). This positioning of the lancet system relative to the lancing aid and consequently relative to the drive plunger ensures that only a lancet that has not yet been used is employed for

the next lancing operation. An advance of the lancet system in only one direction of rotation and a mechanism that allows no more than one rotation of the lancet system by 360° can be added as required in order to prevent already used lancing aids from being used again.

[0060] FIG. 7 shows another embodiment of a lancet system that is in the form of a round magazine housing. The needle ~~body~~ housing design has several parts similar to the figures that have already been described. The sterile protection and needles are also arranged as already described and thus a more detailed description is omitted here. Similar to the system described in FIG. 5 the blocking mechanism shown in FIG. 7 is also actuated when the lancet system is inserted into the lancing aid. For this purpose the needle ~~body~~ housing (2a) has a blocking mechanism (31) that is in the form of an outer ring that surrounds the upper section (35) of the needle ~~body~~ housing. When positioned at this position the blocking mechanism (31) essentially covers the elastic arms (90) that are located in the upper portion of the needle ~~body~~ housing (35). As a result the elastic arms (90) are pressed into the recess (95) of the needle ~~body~~ housing (2a). The blocking mechanism (31) also has a circular protrusion at its lower end that enlarges the circumference of the needle ~~body~~ housing (2a) at this position. If the lancet system is inserted into a lancing aid, the circumference of the lancing aid is selected such that the ring (96) cannot be inserted into the lancet system. The ring is pressed downwards relative to the needle ~~body~~ housing into the area of the lancet tips when the lancet system is inserted into the lancing aid by means of a lower edge (97) acting as a counter-flange for the lancing aid housing. As a result the spring-mounted locking arms (90) are released from the ring. The resting arms are now in a spread state in the lancing aid and are pressed against the inner housing wall (98) of the lancing aid. When a used lancet system is removed from the lancing aid, the locking arms (90) slide along the sloping housing wall (98) in a tapered area of the lancing aid housing and are firstly pressed into the recess (95) of the needle ~~body~~ housing due to the slanting wall (98). Hence the lancet system can be readily removed from the tapered area of the lancing aid. The used lancet system is subsequently present in a changed form as shown in FIG. 7c. When the system is reinserted into a lancing aid the locking arms (90) are now spread and thus the circumference of the needle ~~body~~ housing (2a) is enlarged in the area (35) thus preventing an insertion of the lancet system into the front narrowed area of the lancing aid.

[0061] As any person skilled in the art will recognize from the previous description and from the figures and claims, modifications and changes can be made to the preferred

embodiment of the invention without departing from the scope of the invention as defined in the following claims.

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